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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,969	02/16/2001	Bernard Charles Sherman	PT-1858001	3343

23607 7590 11/26/2003

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EXAMINER

KIM, VICKIE Y

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 11/26/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/783,969

Applicant(s)

SHERMAN, BERNARD CHARLES

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,17-22,24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,17-22,24 and 25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of application

1. The application was withdrawn from issue(see paper no. 21). There are some issues that must be addressed and resolved before the issuance. The claims 1, 17, 18-22 and 24-25 are currently pending and presented for the examination.

Claim Rejections - 35 USC § 112

New Matter

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The claims 1, 17, 18-22, 24-25 are directed to a microemulsion preconcentrate consisting essentially of a cyclosporin dissolved in a solvent system consisting of fully acetylated monoglyceride lipophilic solvent having a minimum acetylation of 96%, a hydrophilic organic solvent and **a synergistic mixture of two surfactants**, wherein the microemulsion preconcentrate yields a droplet size in an emulsion of less than 2000 Å as measured by light transmittance through a cell. However, there is no support found in the instant specification for the phrase (i.e. a synergistic mixture of two surfactants) whereas the instant specification teaches a synergistic mixture of certain preferred surfactants with other surfactants which are specifically recited in the page 9. The mixture of any two surfactants may not necessarily produce the synergism because the specification specifically teaches that the synergism is only produced when those

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preferred surfactants are mixed with other surfactants, the claimed invention is different from the invention of original description. There is no sufficient evidence to convey to one of ordinary skill in the art that applicant was in possession of the claimed invention. Therefore, the claims fail to comply with the written description requirement.

4. Claims 1, 17, 18-22, 24-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for enhanced dissolving activity from the mixture of two surfactants, does not reasonably provide enablement for synergism induced from the mixture of two surfactants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. However, the synergism should be very different from additive effect where the instant specification fails to prove the synergism produced from the mixture of preferred surfactant and other surfactant. Although the instant specification teaches an example with one surfactant(see example at page 12), there is no comparison study result shown to prove the synergism from the said surfactant mixtures used(examples 1-8 at page 13). Thus, at the time of the invention, one of ordinary skill in the art could not decide how the claimed invention is different (superior) than other microemulsions known or available in the field(e.g. Neoral® or Hauer et al(US 5,343,625)). For the reason set forth above, the claimed invention is not enabled by the specification as originally filed without undue experiment.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 17, 18-22, 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauer et al(US 5,343,625).

As mentioned in the previous office action, US'625 teaches a pharmaceutical composition containing a cyclosporin as an active agent in the form of "microemulsion pre-concentrate" and "emulsion pre-concentrate", see abstract. US'625 also teaches a size of droplet less than 2000A, solvents including both hydrophilic solvents such as transcudrol and lipophilic solvent such as MYVACETtm (as evidenced by applicants own admission(see page 7 of instant specification), and a mixture of two surfactants(e.g. hydrophilic and lipophilic surfactants, see col.9, line 40-col.12, line 15). It is noted that MYVACETtm is acting not only as a lipophilic solvent that is fully acetylated monoglyceride having a minimum acetylation of 96% but also as a lipophilic surfactant. Thus, all the critical elements required by the instant claims are suggested by the cited reference. Although the claimed invention is not exemplified in the patented reference, it would have been obvious to one of ordinary skill in the art to make such composition because it is readily apparent that a combination of two or more would be better to enable higher concentration of the drug and adequate ease of dispersion, especially due to their dual functionality which acts as both surfactant and solvent as taught by the cited reference. Since the cited reference includes two surfactants, the synergistic effect is inherently possessed feature and naturally occurring when these surfactants

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are combined together, thus all the claimed invention is obvious and one would have made such modification using the ingredients required by both claims and cited reference and the reasonable expectation of success can be anticipated because the techniques and the skills to make such modification is well within the skilled level of the artisan having ordinary skill in the art, absent evidence to the contrary. Thus, the claimed subject matter is not patentably distinct over the prior art of the record.

Conclusion

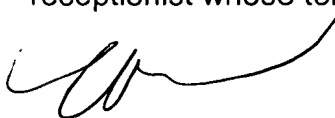
7. No claim is allowed.

8. The new ground(s) of rejection presented in this Office action is necessitated by the amendment entered 7/15/03(see paper No.20). Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Vickie Kim,
Primary Patent examiner
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